K080621



## 510(k) Summary

APR 29 2008

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| Submitter Name:<br>Submitter Address: | European Custom Manufacturing B.V.<br>PO Box 53, NL 5420 AB Gemert, The Netherlands |
| Phone Number:<br>Fax Number: | 31-492-371234<br>31-492-371237 |
| Contact Person: | Rogier Eijck |
| Date Prepared: | 29 November 2007 |
| Device Trade Name: | Fastlock Pacing Wire Extension Cable |
| Common Name | ECG Cables |
| Classification Name,<br>Number &<br>Product Code: | Cable, transducer and electrode, patient (including connector)<br>870.2900<br>DSA |
| Predicate Devices: | CP Medical Disposable Temporary Pacing Cable |
| Device Description and Statement of Intended Use | The Fastlock pacing wire extension cable device provides simple connection between an external pacemaker and pacing wires that are attached to a patient body, in order to transmit low voltage electrical signals between the devices and sensors. The Fastlock product is limited by the Indications for Use of the connected external pacemaker. Intended Use: The Fastlock pacing wire extension cable device is intended to be used as an interface between an external pacemaker and pacing wires, which are attached to a patient body. |
| Summary of Technological Characteristics | The Fastlock pacing wire extension cable consists of an electrical cable with a safety connector at one end that allows electrical connection to the external pacemaker and connectors at the other end that will be attached to the patient's leads. |
| Conclusion | The information discussed above demonstrates that Fastlock product, as effective, and performs as well as or better than the predicate devices. |
| Declarations | This summary includes only information that is also covered in the body of the 510(k).<br>This summary does not contain any puffery or unsubstantiated labeling claims. |

This summary does not contain any raw data, i.e., contains only summary data.
This summary does not contain any trade secret or confidential commercial information.
This summary does not contain any patient identification information.

## Summary of Technical Characteristics

| Feature | FastLock Extension Cable | Disposable Temporary Pacing Cable |
|---|---|---|
| 510(k) Number | | K022075 |
| Manufacturer | European Custom Manufacturing BV | CP Medical, Inc. |
| Classification # & Product Code | 870.2900<br>DSA | 870.2900<br>DSA |
| Intended Use | interface between external pacemaker and pacing wires, which are attached to a patient body. | Interface between various diagnostic and physiological monitoring devices (not manufactured by CP Medical) and disposable sensor devices(not manufactured by CP Medical) which are attached to a patient body. |
| Mode of Action | Connects to pacemaker | Connects to pacemaker |
| Reusable | No | No |
| Method of Clamp Introduction | Male to female connector | Alligator clips |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 29 2008

European Custom Manufacturing BV
c/o Mr. William Greenrose
President
Qserve America, Inc.
220 River Road
Claremont, NH 03743

Re: K080621
Trade/Device Name: Fastlock
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient transducer and electrode cable
Regulatory Class: Class II (two)
Product Code: DSA
Dated: December 13, 2007
Received: March 5, 2008

Dear Mr. Greenrose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K080621

Device Name: Fastlock

Indications For Use:

Fastlock pacing wire extension cable with connectors is indicated for use as an electrical extension cable used to transmit signal from, or power or excitation signal to patient-connected electrodes.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K080621